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Title: AN INCONTINENCE KIT FOR A MALE. ;

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Applicant(s): SQUIBB_SONS INC (US) ;

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IPC Classification: A61F5/44 ;

Equivalents: AU8474082, CA1184818

ABSTRACT:

The device comprises an applicator (10), which is a substantially cylindrical device (11), with a peripheral groove (12, 14) at either end, and a condom-like, elastic incontinence device (10) with a hole (18) at its extremity. The incontinence device is rolled up and placed over one end of the applicator with the rolled up portion in the peripheral groove (14) at one end of the applicator (10). Then, the applicator, with the incontinence device thereon is applied over the penis, and a retaining ring (26) which was held by the peripheral groove (12) at the opposite end of the applicator is rolled off the applicator onto the penis immediately to the rear of the corona whereupon the retaining ring insures the retention of the incontinence device on the head of the penis. The applicator is then removed from the penis, and the incontinence device is rolled back over the penis where it serves as a tube to conduct urine away from the wearer.

- (57) A male incontinence device includes a condom 16 having an outlet hole for urine and a stretchable retainer ring 28 arranged to seat immediately behind the corona, the unstretched diameter of the ring being from 55% to 75% of the maximum diametral dimension of the penis upon which the device is to be worn. The condom preferably covers only the head of the penis. The device may be applied using a tubular applicator having an I.D. greater than the maximum O.D. of the penis with which it is to be used.



FIG. 1

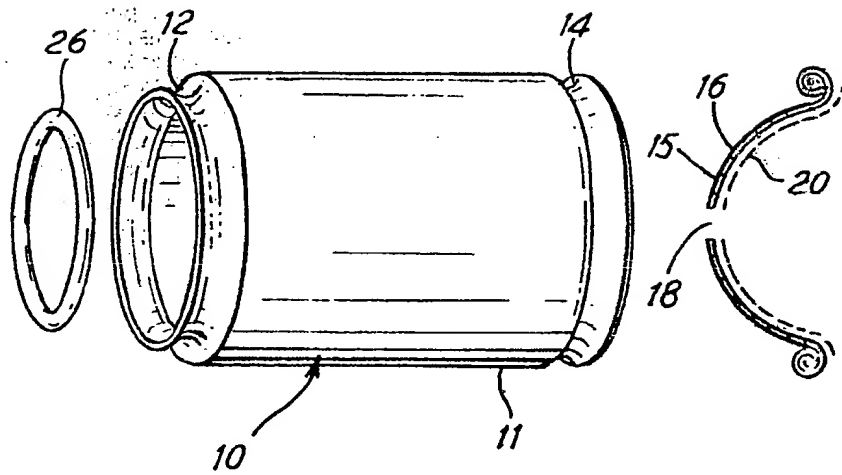


FIG. 2

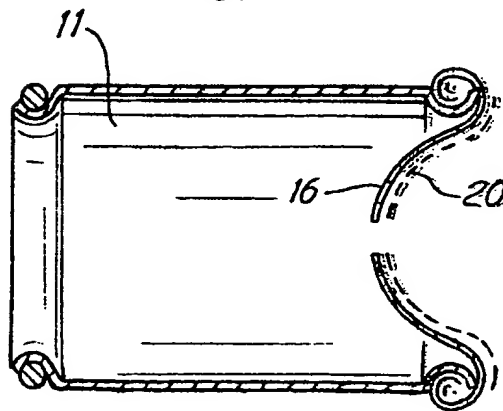


FIG. 3A

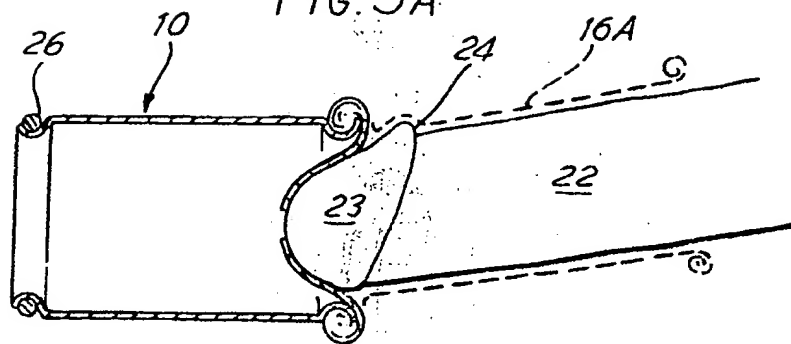


FIG. 3B

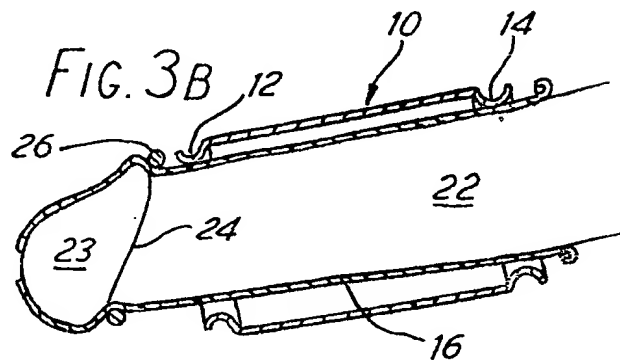
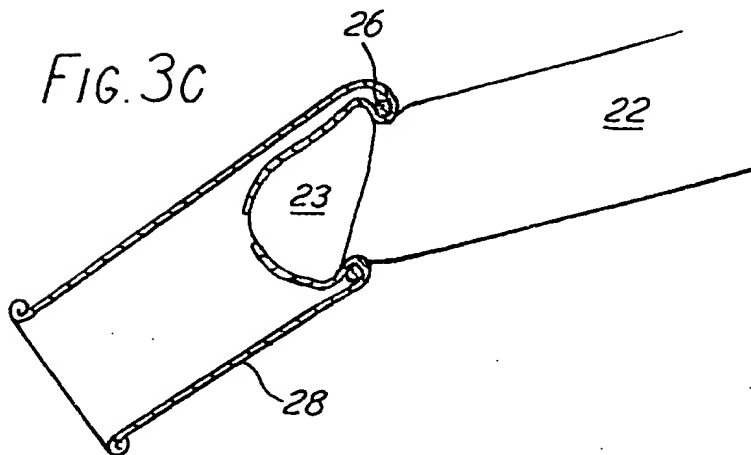
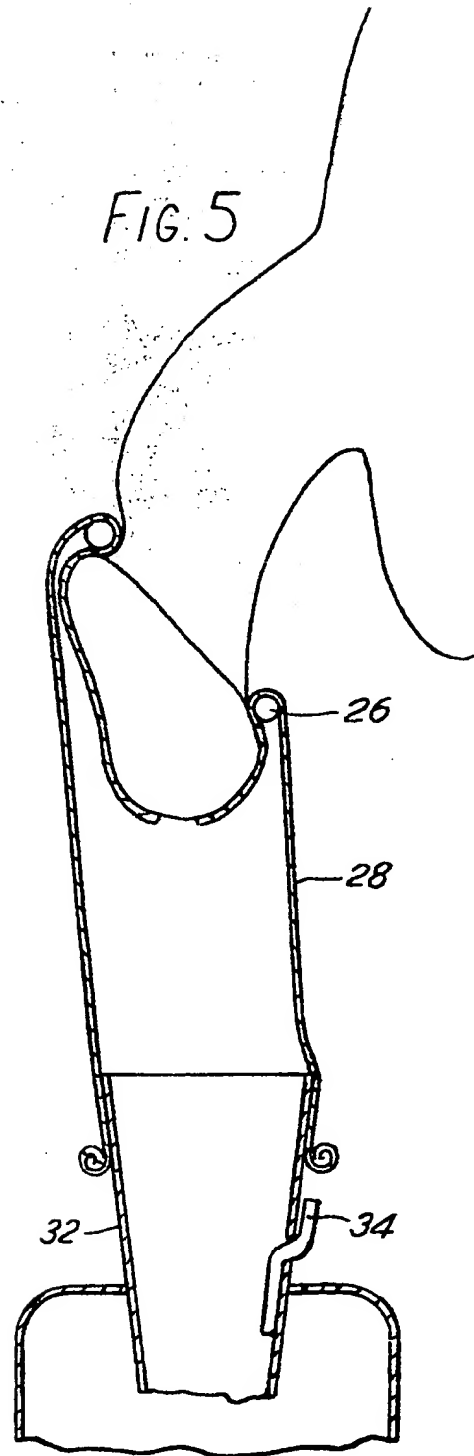
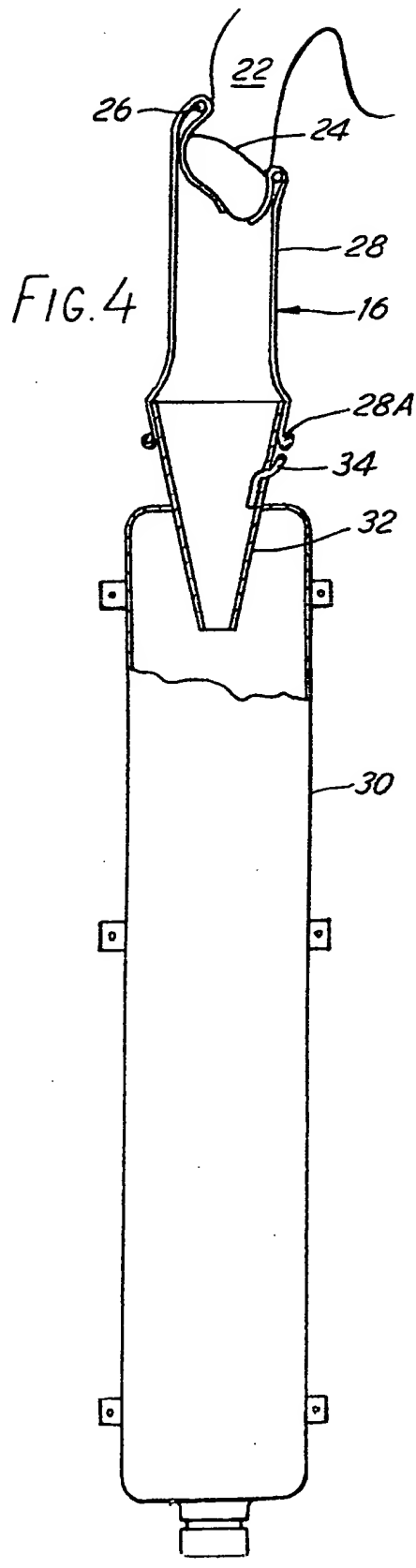
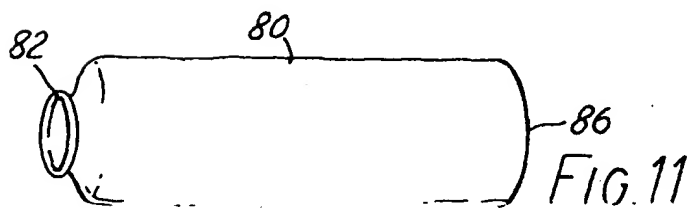
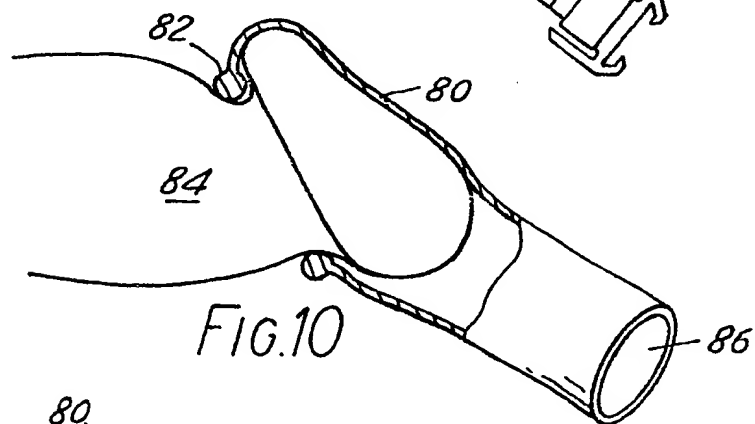
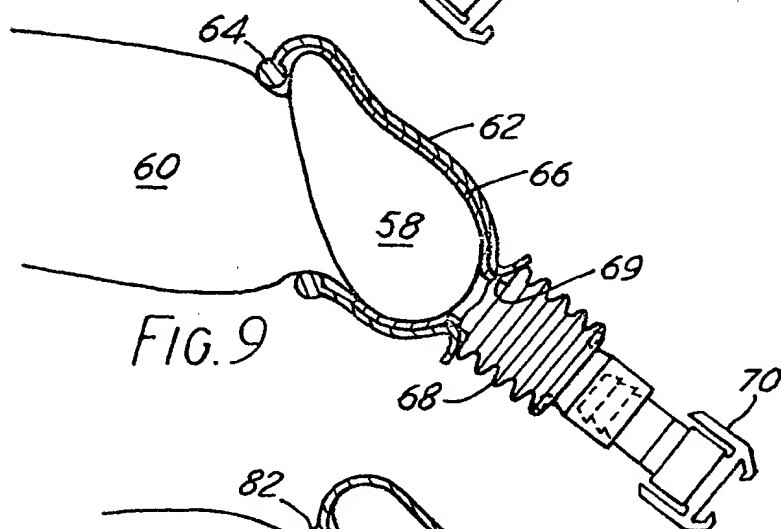
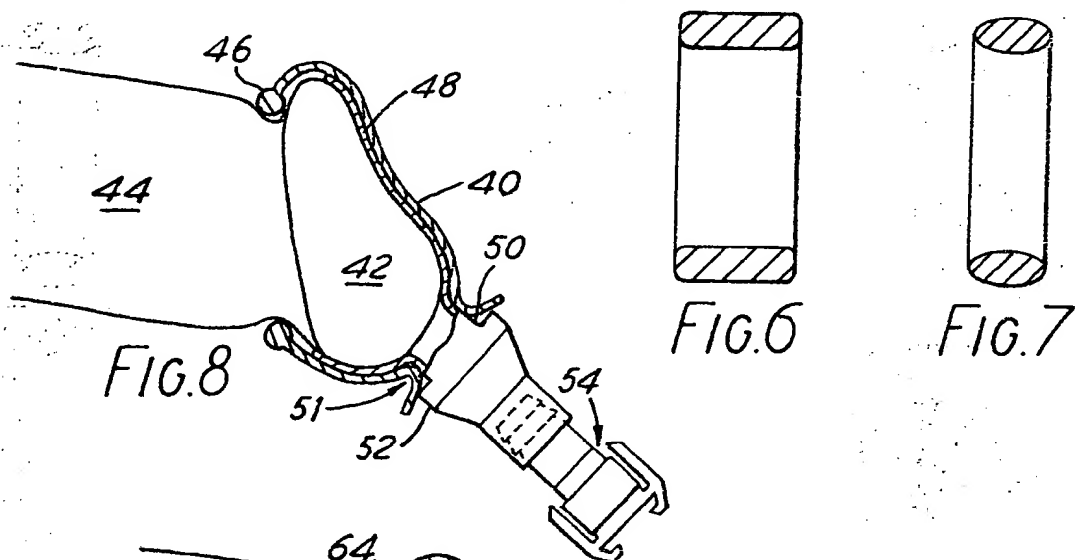


FIG. 3C







SPECIFICATION

Male incontinence device, and kit of parts for same, and method of using same

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This invention relates to a male incontinence device, and kit of parts for same, and method of using same.

There have been a multitude of prior proposals for devices to assist male incontinent personnel, see for example the prior British Patents Numbers 871 862, 994 274, 1 011 517, 1 245 191, 1 274 374, 1 283 616, 1 375 940, 1 459 486, and 1 521 064.

It will be seen from these prior Patents that a wide variety of approaches to the problem of incontinence have been made. Many devices are unsuccessful because they fail to allow the external skin in the genital area to be kept dry. Others fail because of leakage, and yet others fail because the adhesive or sticky tape or binding by which they are fixed on causes skin problems for the wearer, e.g. oedema, maceration, soreness, allergic reactions. Other devices are unsuitable for children where retraction of the penis into the body tissue around the pubic area is likely to occur. Devices which require belts, harnesses, rigid supports and straps are cumbersome to put on and take off, and, in the case of persons in hospital, require much use of scarce skilled nursing time and ability. It is also highly desirable in the case of an adolescent or grown male that the occurrence of an erection while wearing the device should not give rise to dislodgement of the device or pain or discomfort to the user, or damage to his penis. Many devices are too complex or expensive or difficult to manufacture to be contemplated for widespread use.

U.S. Patent Specification No. 2 699 781 of F. E. KOCH suggests a self-carried urinal for male use and this has an inflatable collar or cell disposed at the mouth of a urine-receiving bag. This cell is inflated to grip the shaft of the penis behind the corona, and ribs or roughening are suggested to achieve a firm grip. U.S. Patent Specification No. 2 789 560 of WEIMER discloses a hollow cap (10) of rigid material shaped to conform to the forward end of a penis. This is held on by a rollable sheath (18) of elastomer such as thin latex, which in use is rolled back over and to extend along the shaft of the penis. A tubular insert lining (16) is included for cushioning and to improve the fit of the rigid cap. A somewhat similar device but evidently intended for persons suffering from only slight leakage is shown by H. W. WARNER in U.S. Patent Specification No. 3 648 700; this uses adhesive tape which wraps around the penis shaft to hold it in position. As there is no conduit to remove expelled urine, the device would have to be removed when the user desired to micturate.

In British Patent Specification No. 1 304 544 (STILLEWERNER) there is disclosed a condom-like device which is elastically applied to the penis for use in urinating. A ring (12) is used in its application. Apparently the tube or sleeve (10) tightly embraces

the shaft of the penis. The device has a special thick-walled lower portion (13).

65 U.S. Patent Specification No. 3 394 703 (ORGEL) shows a thin elastic cap or sleeve which directly fits over and snugly engages the glans of the penis. This may in some instances be a self-supporting item (column 2, line 60), but a harness structure is also suggested. The fit is close to the corona (column 2, line 24, 25) and there is an annular collar 8 just behind the corona. An outlet tube 9 is connected to the lower end. As described, the collar 8 is vulcanised in fixed engagement with a connection J, and it is apparent that the ORGEL device is basically a non-porous (imperforate) head with internal seals bonded to a porous sheath which is itself attached to a pubic pad, the latter being attached to body harness. The collar 8 is apparently designed to serve as a support for the seal 15 and an attachment region for the connection J; moreover it is conformable to the neck of the penis. There is no disclosure in ORGEL'S teaching that an elastic ring located immediately behind the corona should be used to reduce the normal circumferential measurement of the penis at this region. In other words, by the application of a ring as disclosed in the present application, the circumference of the corpus spongiosum is closed down. Consequently attachment is not rendered insecure by physiological variation of penile size e.g. due to vasoconstriction or vasodilation. Yet another feature of the ORGEL device is that its application by the user alone appears almost impossible as more than two hands would be required.

From the points of view of simplicity, long term effectiveness, and long term comfort, it is presently believed that a condom-like device of thin flexible material such as latex rubber represents the best way of dealing with the many different problems, and that an expansible ring of rubber or equivalent stretchable material is a simple, cheap and effective way of retaining the device in position on the penis.

According to the present invention, there is provided a male incontinence device comprising a condom having an outlet hole for urine and a stretchable retainer ring arranged to seat immediately behind the corona, the unstretched diameter of the ring being from 55% to 75% of the maximum diametral dimension of the penis upon which the device is to be worn.

Preferably, the unstretched diameter of the ring is from 55 to 65% of the said dimension, and most preferably it is about 60% of the said dimension.

115 The ring may be separate from or integral with the condom.

In one preferred embodiment of the invention, the condom is dimensioned to cover only the head (glans) of the penis. In another preferred embodiment, a length of the condom is folded away from the body over the head of the penis and serves as a conduit for discharged urine.

120 According to one aspect of the invention, there is provided a method of applying and using a male

incontinence device in the form of a penis-fitting condom of rubber or equivalent material and having an open end and a generally closed end with a small urine-passage hole therein, the method comprising
 5 applying the condom to a penis so that the glans is snugly seated in the generally closed end, applying a stretchable retainer ring to the penis externally of the condom so that it encircles the penis to the rear of an adjacent the corona, folding back that portion of the
 10 condom which terminates in the open end over the ring and over the glans, and connecting the open end to a suitable conduit to take away any excreted urine.

According to another aspect of the invention, there
 15 is provided a kit of parts for carrying out such a method, the kit including a penis-fitting tubular sheath of rubber or equivalent material having an open end and a generally closed end, a retainer ring which is stretchable over the glans of the penis and
 20 which in its substantially unstretched condition has a diameter such as to snugly engage behind the corona, and a tubular applicator having an I.D. greater than the maximum O.D. of the penis with which it is to be used.

25 The tubular applicator may have a reduced diameter portion at or near one end constructed to have the retainer ring temporarily stretched thereonto.

Further according to the invention, there is provided a tubular applicator for applying a condom-like
 30 incontinence device to the penis of a user, comprising a hollow tubular body having an O.D. such that the device can be readily stretched thereover and an I.D. that can accommodate the penis in question, a first groove at one end thereof upon which can be stretched a ring located at the mouth of the
 35 condom-like device, and a second groove at the other end upon which can be stretched a retainer ring of rubber or like material.

The invention, in yet a further aspect, consists in a
 40 male incontinence device consisting of a retainer ring in combination with a tubular elastic sheath dimensioned to be stretch fitted over the penis of the wearer, the sheath having a first portion which fits over the glans and has an orifice therein for the pas-
 45 sage of urine in use and, integral therewith, a second portion of length greater than the first portion and having an open end surrounded by a stretchable ring integral with the second portion.

Other aspects of the invention will appear from the
 50 following description, of examples thereof given with reference to the diagrammatic accompanying drawings in which:—

Figure 1 shows a retainer ring, an applicator, and a condom-like device according to a first embodiment
 55 of the invention in rolled condition ready for application to the applicator;

Figure 2 shows the applicator bearing the rolled device and the retainer ring;

Figures 3A-3C show stages in the application of
 30 the condom-like device to the penis of a user

Figure 4 shows a condom-like device worn by a user and connected to a drainage bag; and

Figure 5 shows part of *Figure 4* on a larger scale and illustrates the details of the retainer ring seated

tubular part of the condom-like device serving as a conduit to conduct urine to a drainage device.

Figure 6 is a cross-section, on an enlarged scale, taken in an axial plane, through one form of stretch-
 70 able retainer ring usable in the invention as ring 26 of *Figures 1-5*, ring 46 of *Figure 8*, ring 64 of *Figure 9*, or ring 82 of *Figures 10 and 11*;

Figure 7 is a view similar to *Figure 6* of another form of stretchable retainer ring;

75 *Figure 8* diagrammatically illustrates an embodiment of the invention comprising a glans condom used to secure a cap with an outlet tube;

Figure 9 diagrammatically illustrates a further embodiment of the invention, similar to *Figure 8* but
 80 in which the outlet tube on the cap is of flexible, bellows-type construction; and

Figures 10 and 11 are two diagrammatic views of a further embodiment of the invention, of simple construction for short term use.

85 Referring now to *Figures 1-5*, the applicator 10 consists of a substantially cylindrical shell 11 having peripheral grooves 12, 14 one at each end. A thin-walled condom-like incontinence device 16, herein called a condom, has a hole 18 in its end and is seen
 90 in rolled-up condition in *Figures 1-3*. In use it is stretched gently over the end of the applicator 11 so that its rolled up portion rests in the groove 14 as seen in *Figure 2*. As illustrated, the interior of the head region of the condom 16 is coated with an
 95 adhesive 20 but this is an optional and not an essential feature of the invention. Using the applicator as illustrated in *Figure 3*, the condom is then applied to the head (glans) of the penis 22 and the shank portion of the condom 16 is rolled back along the shaft
 100 of the penis as indicated at 16A in *Figure 3*. The applicator 10, whose minimum internal diameter is comfortably in excess of the outside diameter of the penis with which it is intended to be used, is then moved up the shaft of the penis until its groove or
 105 channel 12 is located just to the rear of the corona 24 of the penis, as seen in *Figure 4*. The user can then slip a rubber ring 26 off the applicator 10 onto the penis immediately in the rear of the corona 24 whereupon the ring 26 (which was stretched to be
 110 placed on the applicator groove 12) contracts to its unextended diameter and is snugly and firmly seated on the penis immediately to the rear of the corona. The remainder 28 of the sheath of the condom is then pulled "inside out", that is to say pulled
 115 away from the wearer's body over the end of the penis, to occupy the position illustrated in *Figure 3C*. Thus the tubular part 28 of the sheath then serves as a tube to conduct away urine to a suitable container
 120 30, *Figure 4* or to a connecting tube. As seen in *Figures 4 and 5*, a connecting cone 32 has the open end of the tubular part 28 stretched over its open end 28A and an air inlet pipe 34 prevents build-up of negative pressure in the system. As an alternative, not shown, the lower end of the cone may be provided with a
 125 coupling element of a coupling such as that disclosed and claimed in our Patent Application No. 81 36811 (Publication Serial No.), to facilitate connection of the male incontinence device to a drainage bag such as that shown in our Patent

It has been found in practice that if the ring 26 has an unstretched diameter of approximately 3/5 of the diameter of the penis with which it is to be employed, then it holds the sheath in place securely in the configuration shown in Figure 5 while at the same time preventing leakage and yet being comfortable to wear for long periods. The location of the retainer ring 26 immediately behind the corona is from an anatomical view point and in the inventor's opinion the ideal location and this is an important feature giving the invention advantages over prior proposals.

Reference has been made above to a relationship of 3/5 or 60% for the unstretched retainer ring diameter as a fraction or percentage of the maximum diameter of the penis upon which the device is intended to be worn. Naturally the advantages of the invention can be secured without employing a mathematically exact 60% relationship; in many cases it will be appropriate and entirely satisfactory if the relationship is from about 55% to about 65%. The retainer ring may be a true toroid, that is to say it may have a circular cross-section taken in a radial plane but good results have also been obtained with a ring in the form of a slightly flattened band, that is a ring having either rectangular or oval cross-section in a radial plane, as illustrated in Figure 6 or Figure 7.

The normal and average diameter of the adult male penis at the postero-coronal point ("neck") is 30 mm.

The normal and average free-flow diameter of the adult male urethra is 6 mm. at the postero-coronal point of the penis.

At this postero-coronal point the vascular spongy tissue encompassing the urethra (the corpora spongiosa) can be effectively contained with an elastic band placed extragenital, circumferential and passive to within 3 times the free-flow diameter of the urethra. Under such conditions there would be no occlusive pressure applied to the urethral wall or vascular tissue of the corpora spongiosa such as to close down the normal diameter of the urethra.

Therefore 3 times the diameter of the open free flow male urethra is a functionally safe diameter for the unstretched diameter of a stretchable retainer ring. This retainer ring will not occlude any substructures nor in practice ride over and off the glans penis at the corona. It provides an excellent fixing means for a glans condom incontinence control device designed to fit sub-prepuceally, whether the condition of circumcision exists or not. In other words this type of fixing is suitable for both the circumcised and uncircumcised patient.

As the measuring of urethral diameters by catheter or sound is an invasive technique of acquiring information for calculating retainer ring size, the following practical and non-invasive method of calculation has been devised.

Urethral diameters can be arrived at by measuring the diameter of the penis at the postero-coronal point and using as a constant 3/5 and 3/4 of this diameter to give practically useful values for a minimum and maximum retainer ring size relative to any urethral diameter. The values are given in Table I.

TABLE I
TABLE OF NUMERICAL VALUES FOR SUITABLE RETAINER RINGS

	POSTERO-CORONAL DIAMETER	RETAINER RING SIZE		RELATIVE URETHRAL DIAMETER
		MIN.	MAX.	
ADULT MALE Intermediate sizes if required	30 mm.	18 mm.	22.5 mm.	6 mm.
ADOLESCENT Intermediate sizes if required	25 mm.	15 mm.	18.75 mm.	5 mm.
CHILDREN	(20 mm. ((15 mm.	12 mm. 9 mm.	15 mm. 11.25 mm.	4 mm. - 3 mm.

It is not essential to the invention that the tubular part of the sheath should be used to conduct away the urine. A comfortable and effective male incontinence device may have a penis head condom secured by a retainer ring, with the condom in turn serving to hold in position a shaped rubber or plastics conduit member. Such an arrangement is illustrated in Figure 8, in which a condom 40 covering only the head (glans) 42 of the penis 44 is secured by a retaining ring 46 which is shown as integral with the condom 40, it could instead be a separate part. The ring 46 in either case has the critical diameter rela-

tionship according to the invention which has been discussed above, in relation to the penis 44. A separate glans cap 48 is held on the penis by the condom 40, the upper part of the cap being shaped to conform to the penis head and the lower part having a peripheral groove 50 and a tubular portion 52. A coupling member 54 may be integral with or secured to the tubular portion 52. The preferred coupling member is either a male or a female coupling element of a connector as disclosed and claimed in our Patent Application No. 61 26211. A tie string secured or an elastic band surrounds the outside of the con-

dom 40 at the point indicated 51 to improve the security against leakage by holding the condom 40 tightly into the groove 50.

A somewhat similar, but alternative, arrangement 5 is shown in Figure 9. The head (glans) 58 of a penis 60 is covered by a glans condom 62, held on to the penis by a retainer ring 64. The ring 64 is of rubber or other stretchable material and may be integral with or secured to the condom 62. A glans cap 66 (which 10 may be made of a medically acceptable and commercially available material known as Plastisol) covers the forward part of the head 58 of the penis and is located within the condom 62. The elasticity of the latter holds the cap 66 snugly and firmly on the end 15 of the penis. A conduit member 68 forms part of the cap 64 and is connected to or integral with a coupling element 70.

The conduit member 68 has a peripheral external groove 69. A tie or tape or elastic band surrounds the 20 condom 62 and holds it into the groove 69 in the same way as described in connection with parts 50 and 51 in Figure 8. The preferred coupling element is either the male or the female coupling element disclosed and claimed in our Patent Application No. 25 81 36811. The conduit member 66 is made of a flexible material and in bellows configuration so that it can bend and is longitudinally extensible. Although a short bellows-form tube is illustrated, it may of course be made longer.

30 A short term emergency male incontinence device is illustrated in Figures 10 and 11. A short length of thin-walled tube 80 such as rubber latex is open-ended at both ends and has a resilient ring 82 fixed to or integral with one end. The ring diameter is 35 within the critical range according to the present invention, and the ring is placed immediately behind the corona of a penis 84 in the manner previously described. The open end 86 of the sheath or tube 80 is connected in any convenient way to a bag or 40 another tube. This device is a cheap and simple device which is useful for a short temporary period until a more sophisticated incontinence device (such as that of Figure 8 or Figure 9) can be fitted. The ring 82 may be a standard elastic band of appropriate 45 unstretched diameter.

An important advantage of the invention as particularly disclosed herein is that it dispenses completely with supporting straps and harness of any kind. This is of particular importance in the case of 50 paraplegics and spina bifida patients with whom all harness are likely to cause tissue trauma due to the fact that such patients have no sensation below the waist and so are unaware of any pressure being applied or any chafing occurring. Moreover in the 55 case of wheelchair patients, the proper adjustment of a harness is difficult.

Another advantage is that a device according to the present invention covers the smallest area of tissue possible so reducing the area where an interface 60 of urine can occur. As is known, the sequel to creation of a urine interface is urine burn and tissue trauma. In bad cases, plastic surgery will be required.

A device for a patient who has no sensation in the 65 pelvic area must also avoid causing pressure and

chafing. The consequences if these are not avoided are erosion of tissue, strictures, and tissue trauma fistulas.

For satisfactory results in most practical cases, the following principles should be followed in the selection of and fitting of retainer rings.

1. They must be at a minimum of 3 times the diameter of the urethra.
2. They must not impede the flow of urine.
- 75 3. They must not occlude the urethra or vascular system of
4. They must not cause pressure irritation to penile tissue.
5. They must not ride over and off the glans 80 penis easily.
6. They must be fitted as a subprepuccial unit and juxtaposed to the glans corona at the neck of the penis.

CLAIMS (Filed on 17 Feb 1982)

85 1. A male incontinence device comprising a condom having an outlet hole for urine and a stretchable retainer ring arranged to seat immediately behind the corona, the unstretched diameter of the ring being from 55% to 75% of the maximum diametral 90 dimension of the penis upon which the device is to be worn.

2. A method of applying and using a male incontinence device in the form of a penis-fitting condom of rubber or equivalent material and having an open 95 end and a generally closed end with a small urine-passage hole therein, the method comprising applying the condom to a penis so that the glans is snugly seated in the generally closed end, applying a stretchable retainer ring to the penis externally of the 100 condom so that it encircles the penis to the rear of and adjacent the corona, folding back that portion of the condom which terminates in the open end over the ring and over the glans, and connecting the open end to a suitable conduit to take away any excreted 105 urine.

3. A kit of parts for carrying out a method according to claim 2, the kit including a penis-fitting tubular sheath of rubber or equivalent material having an open end and a generally closed end, a retainer ring 110 which is stretchable over the glans of the penis and which in its substantially unstretched condition has a diameter such as to snugly engage behind the corona, and a tubular applicator having an I.D. greater than the maximum O.D. of the penis with which it 115 is to be used.

4. A tubular applicator for applying a condom-like incontinence device to the penis of a user, comprising a hollow tubular body having an O.D. such that the device can be readily stretched thereover 120 and an I.D. that can accommodate the penis in question, a first groove at one end thereof upon which can be stretched a ring located at the mouth of the condom-like device, and a second groove at the other end upon which can be stretched a retainer 125 ring of rubber or like material.

5. A male incontinence device consisting of a retainer ring in combination with a tubular elastic sheath dimensioned to be stretch fitted over the penis of the wearer, the sheath having a first portion 130 which fits over the glans and has an orifice therein

for the passage of urine in use and, integral therewith, a second portion of length greater than the first portion and having an open end surrounded by a stretchable ring integral with the second portion.

5 6. A device according to claim 1, 3 or 5 in which the unstretched diameter of the ring is from 55 to 65% of the said maximum diametral dimension.

7. A device according to claim 6 in which the unstretched diameter of the ring is substantially 60% 10 of the said maximum diametral dimension.

8. A device according to claim 1, 3, 5, 6 or 7 in which the ring is integral with the condom.

9. A device according to claim 1 or 5 in which the condom is dimensioned to cover only the head 15 (glans) of the penis.

10. A device according to claim 1, 3, 5, 6 or 7 in which a tubular length of the condom is folded away from the body of the wearer over the head of the penis and serves as a conduit for discharged urine.

20 11. A kit according to claim 3 in which the tubular applicator has a reduced diameter portion at or near one end constructed to have the retainer ring temporarily stretched thereonto.

12. A male incontinence device substantially as 25 herein described with reference to and as illustrated in the accompanying drawings.